

The Federal Circuit stated the standard for determining compliance with the written description requirement as follows:

Although the applicant does not have to describe exactly the subject matter claimed, the description must clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed. The test for sufficiency of support...is whether the disclosure of the application reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter. *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111 (Fed. Cir. 1991).

In this case, the instant specification sets forth methods for increasing the nutritional value of a cereal plant seed. Amino acid composition analysis is described on page 39, lines 7-17 and in Table 1.

Also taught are methods for transforming seed and analyzing seed for the expression cassette and expressed protein. For example, transformation, regeneration, and analysis of transformants are fully described. See particularly pages 14-through 23 (transformation/recovery) and pages 23, line 15 through page 27, line 12 (analysis).

Food and feed are described on page 14, lines 4-6.

The instant specification also sets forth SEQ ID NO:7 and describes barley chymotrypsin inhibitor on page 12 and in plasmid PHP11427 (Seq ID 7) gz::BHL::GZ on page 30 line 18 in the instant specification. Alpha-hordothionin (HT12) is described in the specification on pages 27, line 15 - page 30, line 8 and in Seq ID 2, 3, 4 and 5 (Seq. 2: pBSKP-HT12, Seq. 3: PHP8001gz::HT12::gz, Seq. 4: PHP7999 glb1::HT12::glb1, Seq. 5: PHP5025 wx::HT12::wx). Pea low molecular weight albumin cDNA and gene sequences (Seq. ID Nos. 14 and 15) are described on page 12, lines 7-8, and incorporated by reference from page 11126 of Higgins *et al.* (1986). A maize, sulfur-rich plant protein (Seq. ID Nos. 16-17) is described on page 13, lines 5-6, and incorporated by reference from page 6281 of Pedersen *et al* (1988). A maize, methionine-rich plant protein is described on page 13, lines 6-7, and incorporated by reference from page 362 of Kirihsara (Seq. ID Nos.18-19). A rice, methionine-rich plant protein (Seq. ID Nos. 20-21) is described on page 13, lines 7-8, and incorporated by reference from page 127 of Musumura

(1989). A wheat endosperm purothionin (Seq. ID No. 22) is described on page 12, lines 17-18, and incorporated by reference from Mak and Jones as found in the NCBI database.

As stated above, the sequences and methods using the invention of the invention are fully taught. For example, methods for transforming seed and analyzing seed, methods for increasing the nutritional value, food/ feed, and sequences are fully described. See particularly page 12 and pages 14 through 27. Furthermore, as discussed above, the instant specification sets forth specifics, e.g. endosperm-preferred promoters, polynucleotide encoding a high lysine and high methionine protein, and the like, which describe and define the claimed invention.

3. The Examiner states that "Claims 36-56 are rejected under 35 USC 112, first paragraph, because the specification is enabling only for claims limited to transformed cereal plant seed having an elevated lysine, methionine and cysteine content (about 10% to about 35% by weight compared to untransformed cereal plant seed) comprising the modified hordothionin gene of Seq ID NO:2 (HT-12), vectors, plant cells and transformed plants comprising said modified hordothionin gene." Applicants respectfully traverse this rejection.

In rejecting claims 36-56, the Examiner states that the "... specification is enabling only for claims limited to transformed cereal plant seed having an elevated lysine, methionine and cysteine content... comprising the modified hordothionin gene of SEQ ID NO:2(HT12), vectors, plant cells and transformed plants comprising said modified hordothionin gene." Applicants respectfully disagree.

The MPEP 2164.02 states "Compliance with the enablement requirement of 35 USC 112, first paragraph, does not turn on whether an example is disclosed. All that is required by the law is an objective enablement of the invention, whether by working examples or by the use of broad terminology. **In re Vaeck, 947 F.2d 488, 496, 20 USPQ2d1438, 1435 (Fed. Cir. 1991).**

New Claim 57 claims "A method for increasing the nutritional value of a cereal plant seed comprising: a) transforming a plant cell with an expression cassette comprising a seed endosperm-preferred promoter operably linked to a polynucleotide encoding a high lysine and high methionine protein; b) regenerating a transformed plant from the transformed cell; and c)

recovering transformed seeds having increased lysine and methionine compared to a corresponding non-transformed seed. Support for this amendment is found in the original claims and on pages 14-27.

Claim 59, as amended, claims "A seed from a cereal plant which has been transformed to express in the endosperm of the seed a high lysine and high methionine protein, wherein the seed comprises elevated levels of lysine and methionine compared to a corresponding non-transformed plant." Example 4, page 36 details methods of amino acid analysis of seeds. Methods for separating and preparing the embryo and endosperm are detailed on page 37, lines 1-4. Further support for this claim is found in original claim 19 and on pages 14-27.

Claim 61, as amended, claims "An expression cassette comprising an endosperm-preferred promoter operably linked to a nucleotide sequence encoding a high lysine and high methionine protein." Several sequences detail expression cassettes with endosperm-preferred promoter and operably linked to sequences such as those described in Claim 61. Furthermore, support for this claim is found in original claim 13 and on pages 17, lines 8- page 18, line 18.

In light of the supporting specification and comments *supra*, applicant believes that claims 57-74 are enabled.

4. The Examiner states that Claim 46 is rejected under 35 U.S.C.112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention."

Claim 46 has been cancelled. However, detailed support including page and line numbers supporting claim 46 were detailed in the preliminary amendment of 3/15/00 at the bottom of page 4 and the top of page 5 and as follows:

"-page 12, lines 7-8, the pea low molecular weight albumin cDNA and gene sequences are found on page 11126 of Higgins *et al.* (1986) (Seq. ID Nos. 14 and 15)....

-page 12, lines 17-18, a wheat endosperm purothionin is found in Mak and Jones as found in the NCBI database (Seq. ID No. 22)."

5. The Examiner states that "Claims 36-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention."

Claims 36-56 have been amended and rewritten to include proper antecedent basis, clarity, correct comparisons and to remove "further comprising" and thus the rejections have been rendered moot.

Rejections under 35 USC 102

6. The Examiner states that "Claims 36-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Falco *et al.* (U.S. Patent 5,773,691)." Applicant respectfully traverses.

New Claim 57-74 distinguish over Falco by reciting "... high lysine and high methionine ...". MPEP 706.02 states "... for anticipation under 35 USC 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly." Falco teaches high lysine but not methionine, and therefore does not anticipate the present claims.

Rejections under 35 USC 103

7. The Examiner states "Claims 36-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rao *et al.* (U.S. Patent 5,885,802) or Rao *et al.* (U.S. Patent 5,990389) in view of Rao *et al.* (U.S. Patent 5,885,801 and Applicant's Admission)." Applicant respectfully traverses.

The Examiner also states that the claimed invention is indefinite.

Applicant believes the reasons for the Examiner's rejection for indefiniteness have been addressed at item 5 and in the new claims *supra* and that the rejection has been overcome.

The Examiner states that the "[A]applicant admits that endosperm-specific promoter, including the zein promoter and waxy promoter, were well known in the art at the time of Applicant's invention..."

The MPEP states "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure." Therefore the applicant's disclosure cannot be used to make the suggestion of the claimed combination of endosperm-preferred promoter and high methionine and high lysine protein.

The Examiner states that "It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the invention of Rao ('802) or Rao ('389)...because that would further enhance the nutrional [nutritional] value of the plants and plant products. Applicant respectfully traverses.

MPEP 2141, Basic Considerations which apply to Obviousness Rejections, states that the references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination. Rao broadly discloses engineered proteins. The present claims distinguish over Rao by reciting the claimed combination of endosperm-preferred promoter and high methionine and high lysine protein.

8. The Examiner states "Claims 36-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jaynes *et al.* (U.S. Patent 5,811,654) in view of Applicant's Admission."

The Examiner states that the claimed invention is indefinite.

Applicant believes the reasons for the Examiner's rejection for indefiniteness have been addressed at item 5 and in the new claims *supra* and that the rejection has been overcome.

The Examiner states that the "[A]applicant admits that endosperm-specific promoter, including the zein promoter and way promoter, were well known in the art at the time of Applicant's invention..."

The instant application cannot be used to suggest the desirability of making the combination. The MPEP states "The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's

disclosure." Therefore the applicant's disclosure cannot be used to make the suggestion of the claimed combination of endosperm-preferred promoter and high methionine and high lysine protein.

The Examiner states that "[I]t would have been prima facie obvious to one of ordinary skill in the art...to modify the invention of Jaynes to direct expression of the modified gene to the endosperm" Applicant respectfully traverses.

Section 2143 of the MPEP states that there are three basic requirements of a Prima Facie Case of Obviousness that must be met. "First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations."

First, there is no suggestion in Jaynes to combine the subject of the Jaynes invention with an endosperm-specific promoter. In fact, Jaynes teaches away from endosperm-preferred expression by suggesting the desirability of whole plant expression by stating "promoters such as CaMV 19s, CaMV35s and the like are contemplated as being suitable in most plants." (col.6, lines 54-56). The CaMV promoters are not endosperm-preferred.

Furthermore, the suggestion to make the claimed combination and the reasonable expectation of success cannot be found in the applicant's disclosure.

Second, Falco teaches away from success by stating "[L]ysine catabolism is expected to be much greater in the endosperm than the embryo and this probably prevents the accumulation of increased levels of lysine in seed expressing *Corynebacterium DHDPS*...." (col. 88, lines 37-40). Finally, the Jaynes reference does not teach or suggest the claim limitations of an endosperm-preferred promoter and a high lysine and high methionine protein.

The three basic requirements of a Prima Facie Case of Obviousness have not been met, therefore claims 57-74 distinguish over Jaynes.

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Remarks

In light of the foregoing remarks, withdrawal of the outstanding rejection and allowance of all of the remaining claims is respectfully requested.

Respectfully submitted,

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